

REMARKS

Applicants wish to thank the Examiner for the notation in the Advisory Action clarifying the status of the IDS submission of February 26, 2004.

Claims 1-10 and 26-33 are currently pending and the claims have now been amended to further specify that the "resistant starch" is "amylase resistant starch." This language is supported at Page 8, lines 3-5 and elsewhere and is believed to address the Examiner's concerns regarding the meaning of the claims. Accordingly, the amendments make clear that the claims pertain to the amylase resistant proportion of starch components and distinguish over prior art which discloses compositions having lesser proportions of amylase resistant starch.

I. Outstanding Rejections

Claims 1-5, 7-10, 26-28 and 30-33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Laughlin et al., U.S. Patent No. 5,470,839.

Claims 1-10 and 26-33 stand rejected under 35 U.S.C. § 103(a) over Laughlin in view of Watanabe, U.S. Patent 5,300,311 and Garg, American Journal of Clinical Nutrition, 1998.

II. Applicants' Invention

The inventors have shown that consumption of a diet high in resistant starch and unsaturated fats or lipids results in desirable effects on carbohydrate and fat metabolism. In particular, the inventors have shown beneficial results resulting from diets which replace at least 10% of an individual's daily carbohydrate intake with amylase resistant starch and at least 10% of the individual's saturated fat intake with unsaturated fat.

III. Patentability Arguments**A. The Rejection Under 35 U.S.C. §102(b) over Laughlin et al. Should be Withdrawn.**

The anticipation rejection over the dietary formulation of Laughlin should be withdrawn because Laughlin fails to disclose replacement of "at least 10% of an individual's daily carbohydrate intake with amylase resistant starch." While Laughlin teaches a dietary formulation comprising 23g of high amylose starch (which high amylose starch comprised 23% (23g/100g) of the formulation's carbohydrates), only a small fraction of high amylose starch (7.5% to 22%) is amylase resistant starch. (See the Declaration of Ian Brown, Ph.D.) Because Laughlin fails to disclose a diet in which amylase resistant starch would exceed 5% (i.e., $23\% \times 22\% = 5\%$), it cannot anticipate Applicants' claims and the rejection under 35 U.S.C. § 102 should be withdrawn.

B. The Rejection Under 35 U.S.C. §103(a) over Laughlin et al. in View of Watanabe and Garg Should be Withdrawn.

The obviousness rejection over Laughlin in combination with Watanabe and Garg should also be withdrawn. Laughlin fails to disclose a diet replacing at least 10% of an individual's carbohydrate intake with resistant starch. In fact, when Laughlin discloses using 23g of high amylose starch (see the first Example Table), this provides no more than 5 grams of amylase resistant starch when the high amylose starch is 80% amylose, which has a maximum of 22% resistant starch. (Laughlin actually only teaches high amylose starch that is 25% to 75% amylose which have even lower resistant starch contents.) Moreover, Laughlin fails to suggest levels of amylase resistant starch higher than 5% in its formulations. While, Laughlin discloses using high amylose starch it does not teach doing so at a level that would result in replacing at least 10% of an individual's carbohydrate intake with amylase

resistant starch. While Laughlin acknowledges that high amylose starch contains resistant starch it does not address the issue of the variability in the proportions of high amylose starch that is amylase resistant. Without such discussion, it is clear that Laughlin is not concerned with the proportions of starch which are amylase resistant. Thus, Laughlin fails to recognize the importance of the amylase resistant starch content of the high amylose starch and the advantages provided by using resistant starch according to Applicants' invention.

Neither Watanabe nor Garg, make up for the deficiencies of Laughlin with respect to independent claim 1 of the applications. Watanabe is directed to a method of modifying wheat flour as an alternative to high amylose maize (amylomaze starch) because of problems with regard to its taste and texture. (see col. 1, lines 49-56) In this manner, Watanabe teaches away from elevating the content of high amylose maize in compositions such as Laughlin's and would not lead one to modify Laughlin to arrive at the claimed invention.

Garg also fails to make up for the deficiencies of Laughlin in making the claimed invention obvious. Garg provides a contrasting comparison between a high-carbohydrate diet and a monounsaturated diet. Garg finds that compared with high-carbohydrate diets, high monounsaturated fat diets improve lipoprotein profiles as well as the glycemic profile (see page 581, col. 2, lines 26-28) and concludes that a diet rich in cis-monounsaturated fats may be advantageous for improving lipoprotein and glycemic profiles in patients with diabetes mellitus (see page 581, col. 2, lines 45-47). Garg does not disclose or suggest a diet comprising resistant starch and does not suggest that a diet high in monounsaturated fats should be combined with any other diet. For this reason, Garg fails to make up for the deficiencies of Laughlin with respect to independent claim 1.

In addition, the obviousness rejections of claims 6 and 29 directed to treating individuals suffering from obesity should be withdrawn because Noakes et al., *The American Journal of Clinical Nutrition*, Vol. 64, pages 944-951 (1996) discussed in the previous Office Action and the response filed October 17, 2003 teaches away from replacing carbohydrates with resistant starch in diets for hypertriglyceridemic subjects who are overweight. As discussed previously, Noakes et al. teach that replacing carbohydrates with resistant starch in a diet: 1) showed no benefit in insulin sensitivity or plasma lipid responses, 2) caused dyslipidemia to worsen, and 3) accentuated the risk of coronary artery disease. This teaches away from Applicants' discovery that replacing carbohydrates and lowering fats in a diet has the benefits of a) reducing plasma leptin concentrations, b) lowering the incidence or risk of non-insulin dependent diabetes mellitus, and c) reducing post-prandial glucose and/or insulin levels.

Specifically, Noakes et al. teach that replacing as much as 25% of an overweight hyperglyceridemic subject's daily carbohydrate intake with resistant starch does not have a positive metabolic effect on plasma lipids and that replacing as much as 33% had only a small reduction in plasma insulin concentrations. (See page 8, third paragraph). In addition, Noakes et al. suggest that such replacements in combination with changes in fat intake can cause dyslipidemia to worsen. Specifically, Noakes et al. teach that:

"other studies that have made similar dietary changes in carbohydrate and fat (8,9) or fibre separately have not shown any benefit in insulin sensitivity or plasma lipid responses and in fact, dyslipidemia has been shown to worsen."
(See Abstract, Lines 15-18).

Accordingly, the cited references fail to teach that replacing as little as 5% of an individual's daily carbohydrate with resistant starch in combination with replacing at least

10% of an individual's saturated fat intake with unsaturated fat would be successful in achieving the health benefits recited in the claims of the present invention. Accordingly, the rejections over Laughlin et al., either alone or in combination with Watanabe and Garg should be withdrawn and each of claims 1-10 and 26-33 should be allowed.

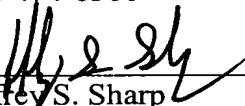
CONCLUSION

For all of the foregoing reasons, the final rejection should now be withdrawn and an notice of allowance of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN LLP
6300 Sears Tower
233 South Wacker Drive
Chicago, Illinois 60606
312-474-6300

By:


Jeffrey S. Sharp
Registration No. 31,879
Attorney for Applicants

February 10, 2005